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(12) **United States Patent**
Houser et al.

(10) **Patent No.: US 6,293,955 B1**
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(54) **PERCUTANEOUS BYPASS GRAFT AND SECURING SYSTEM**

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(73) Assignee: **Converge Medical, Inc.**, Pleasanton, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/415,776**

(22) Filed: **Oct. 8, 1999**

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/644,084, filed on Aug. 22, 2000, which is a continuation of application No. 08/932,566, filed on Sep. 19, 1997, now Pat. No. 6,149,681, which is a continuation of application No. 08/966,003, filed on Nov. 7, 1997, now Pat. No. 5,989,276.

(60) Provisional application No. 60/030,733, filed on Nov. 8, 1996, and provisional application No. 60/026,592, filed on Sep. 20, 1996.

(51) **Int. Cl.**[7] **A61B 17/08**; A61F 2/06

(52) **U.S. Cl.** **606/153**; 623/1

(58) **Field of Search** 606/153, 191, 606/192, 194, 198, 151, 152; 623/1.11, 1.12, 1.36

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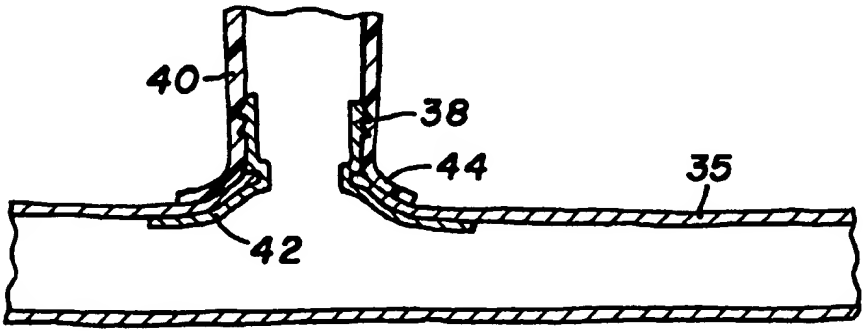
(57) **ABSTRACT**

A bypass graft incorporates fixation mechanisms at its opposite ends, for securing these ends to different locations along a blood vessel, or alternatively to different locations wherein one of the locations is a different vessel or an organ defining a cavity. Mechanical fixation features such as collets or grommets can be employed, enhanced by delivery of an electrical current sufficient to heat surrounding tissue to form a thermal bond. A graft deployment system includes a tissue dilator and a needle for perforating tissue, mounted coaxially within the dilator. Intralumenal systems further include a catheter for containing the dilator.

20 Claims, 13 Drawing Sheets



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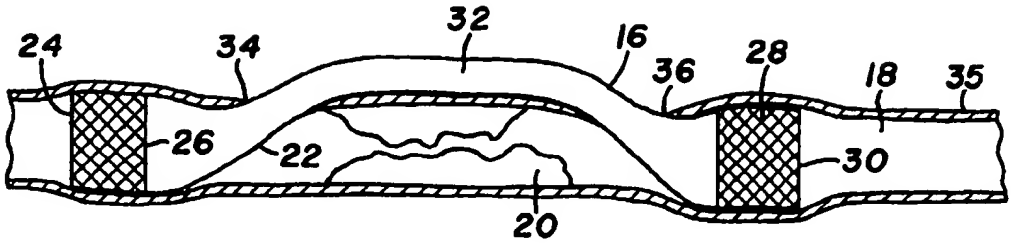


FIG. 1

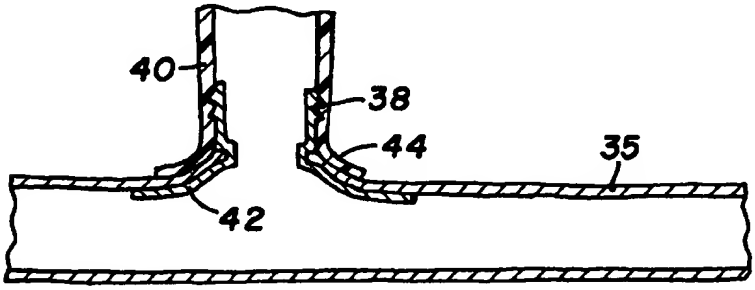


FIG. 2

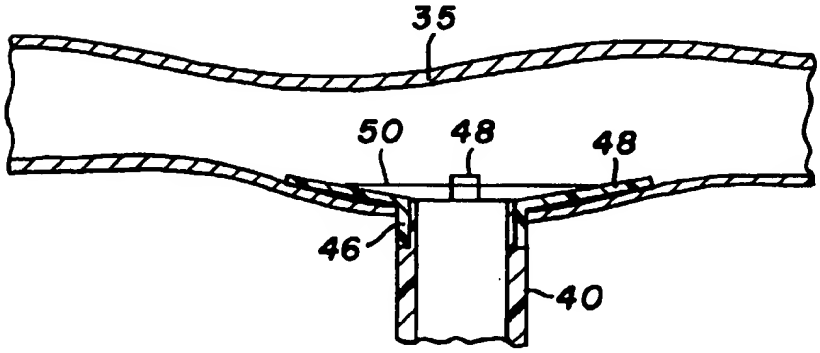


FIG. 3

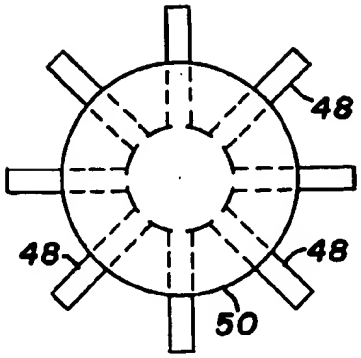


FIG.4

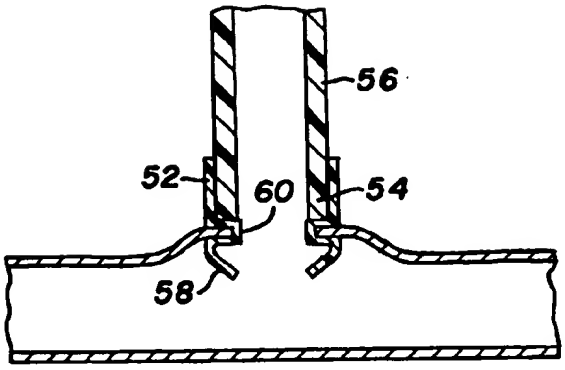
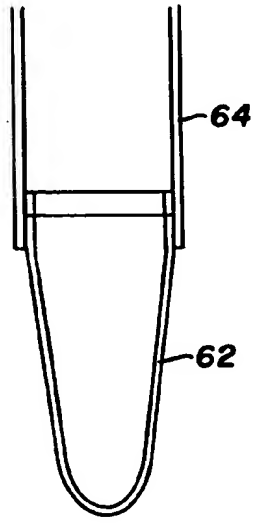


FIG.5



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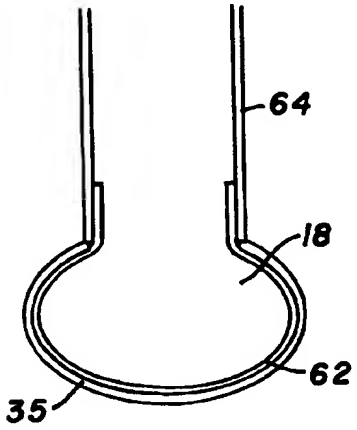


FIG.7

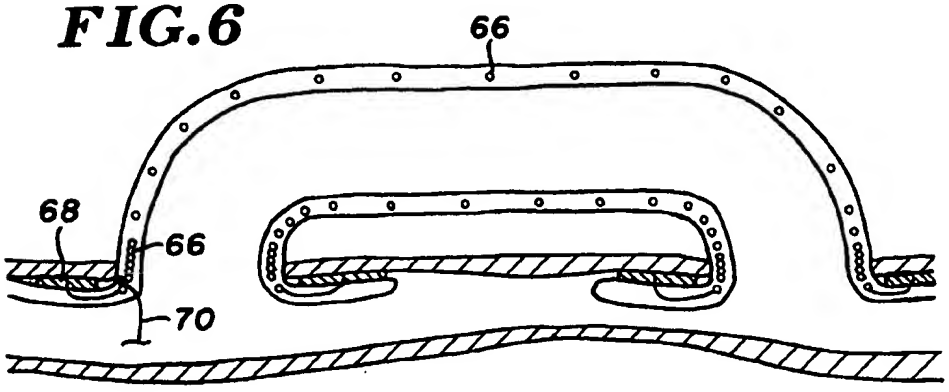


FIG.8

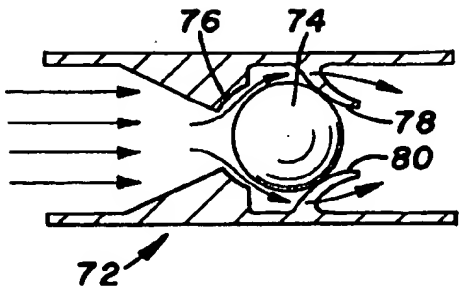


FIG.9

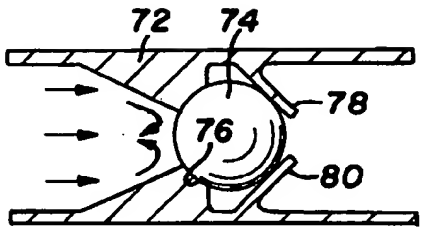


FIG.10

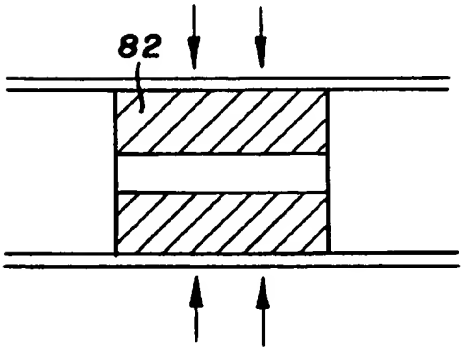


FIG.11

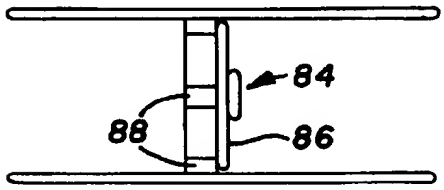


FIG.12

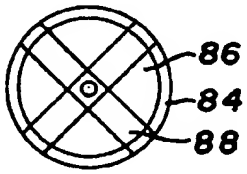


FIG.13

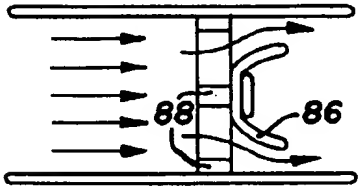


FIG.14

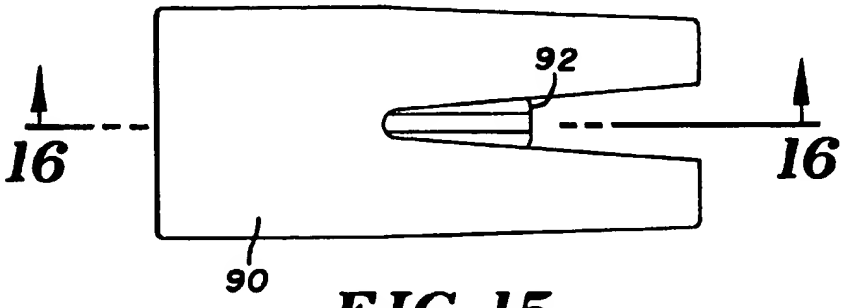


FIG.15

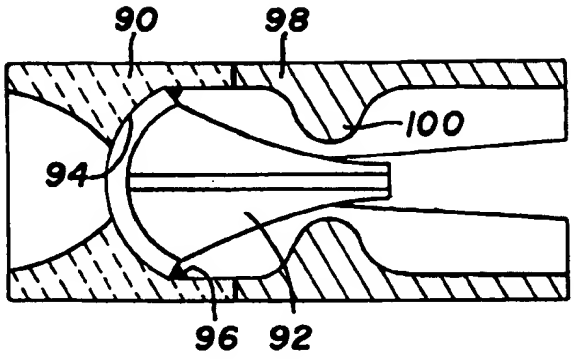


FIG. 16

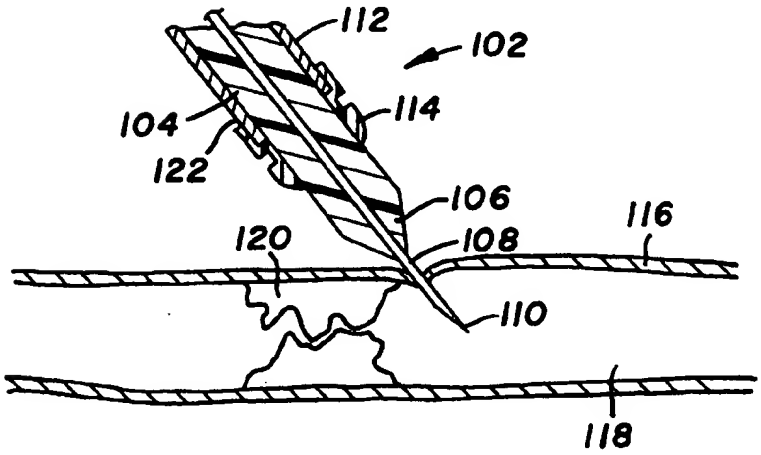


FIG. 17

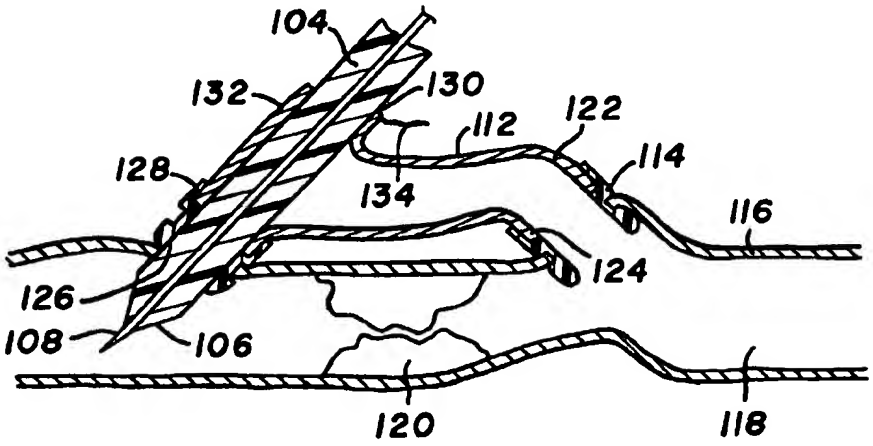


FIG. 18

FIG. 19

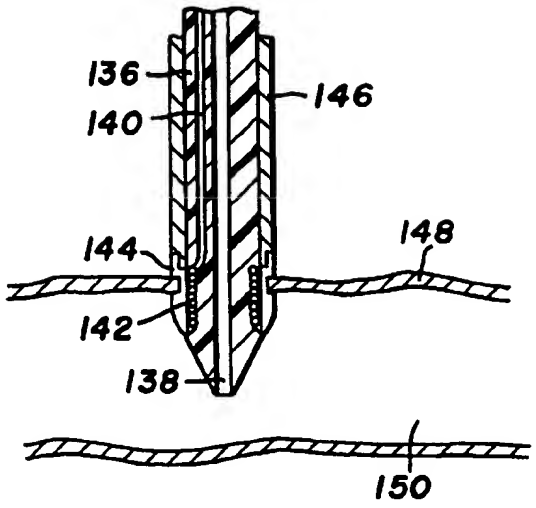
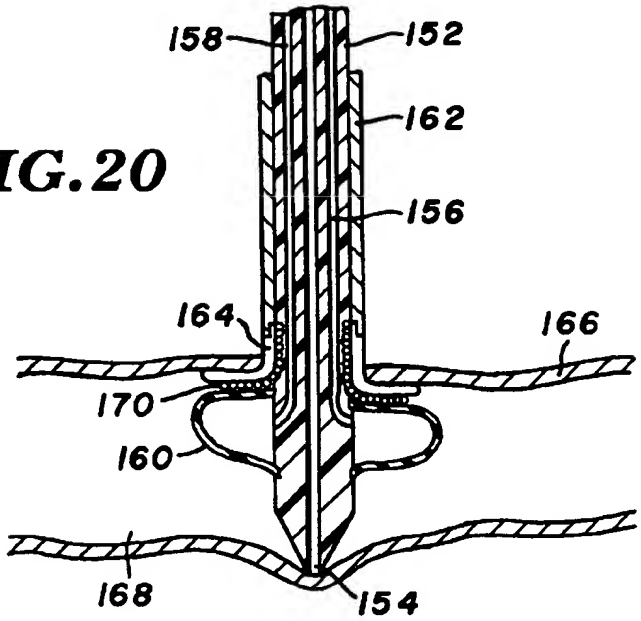


FIG. 20



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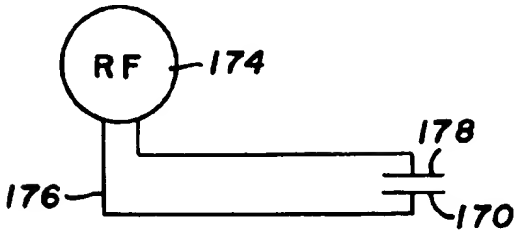

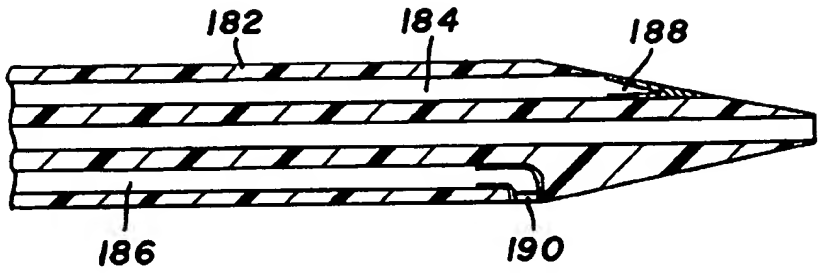

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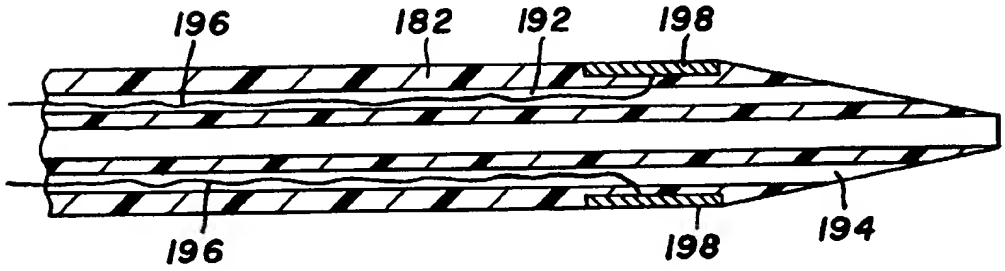

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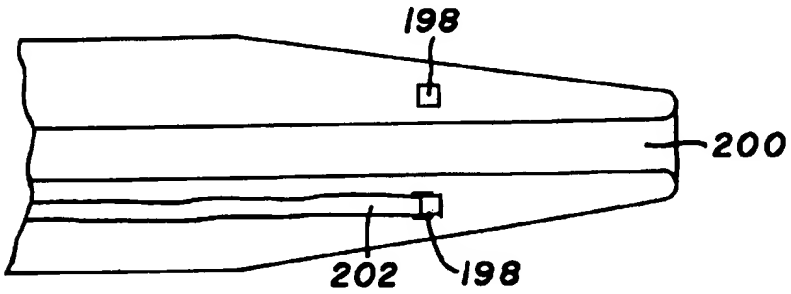
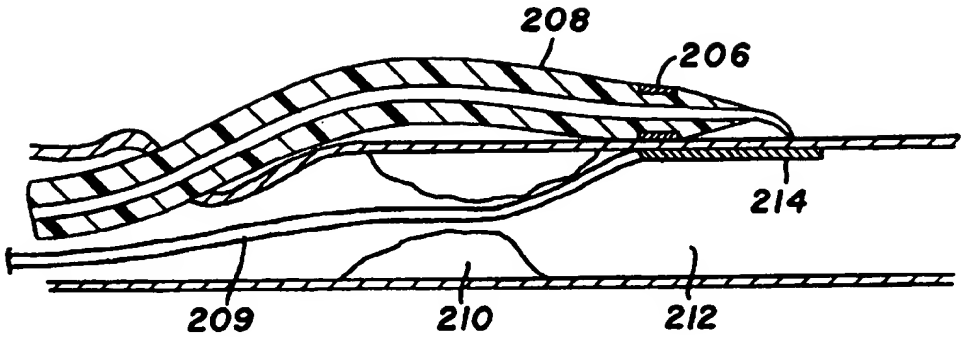


FIG. 24



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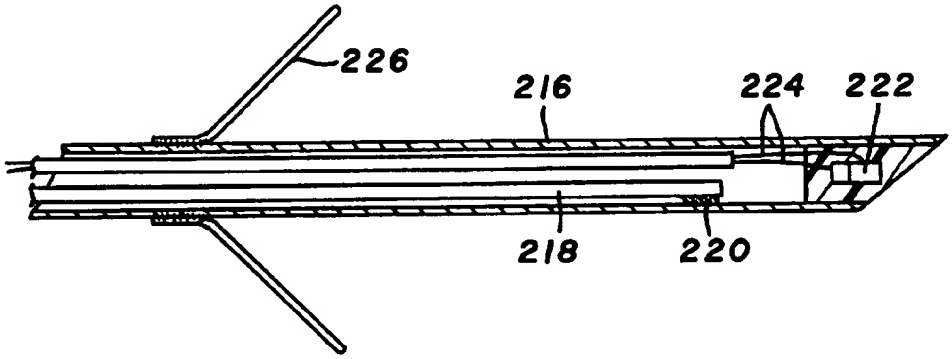


FIG. 26

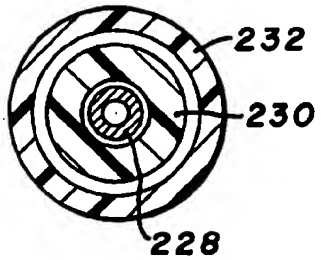


FIG. 27

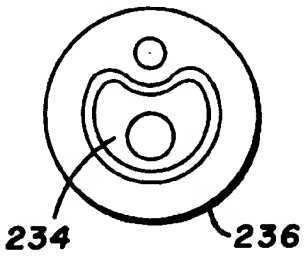


FIG. 28

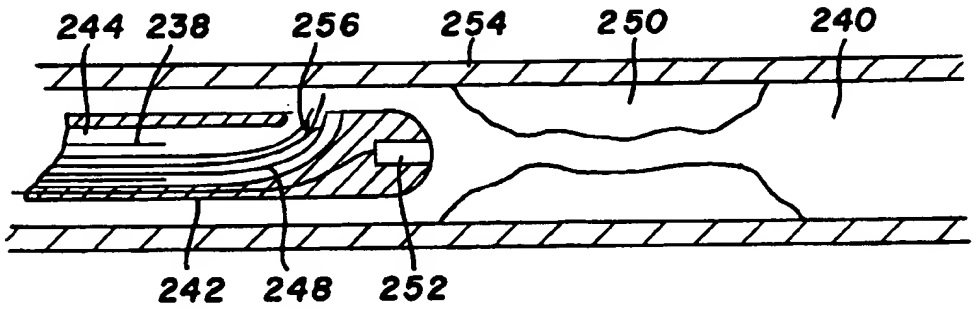


FIG. 29a

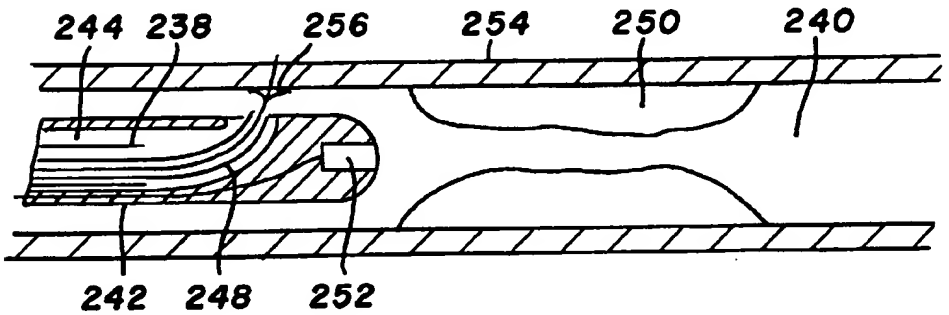


FIG. 29b

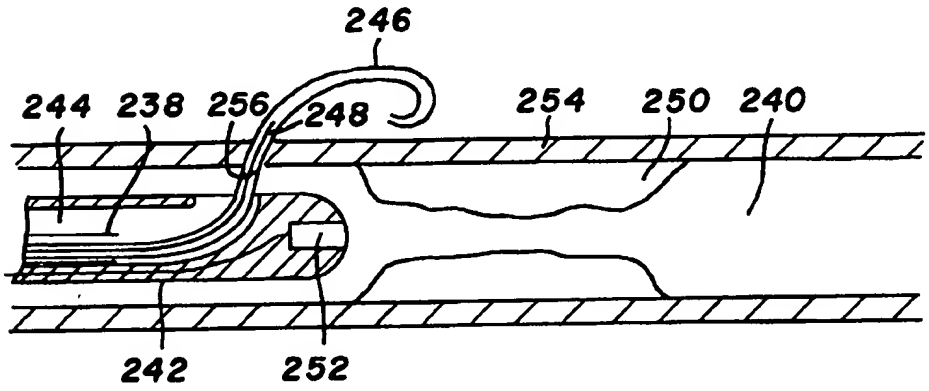


FIG. 29c

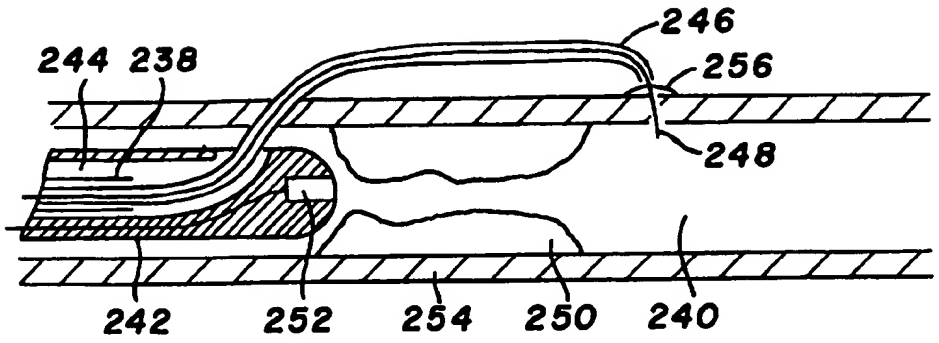


FIG. 29d

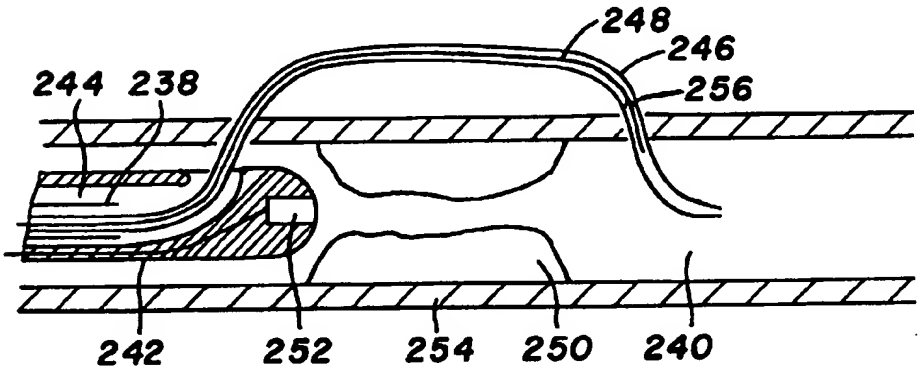


FIG. 29e

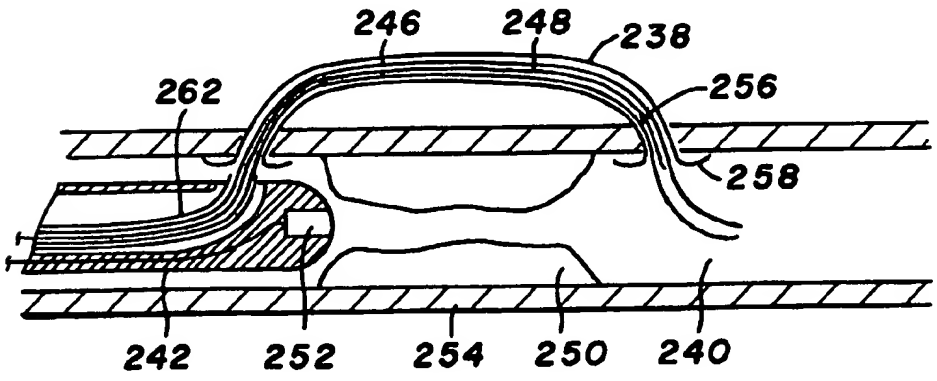


FIG. 29f

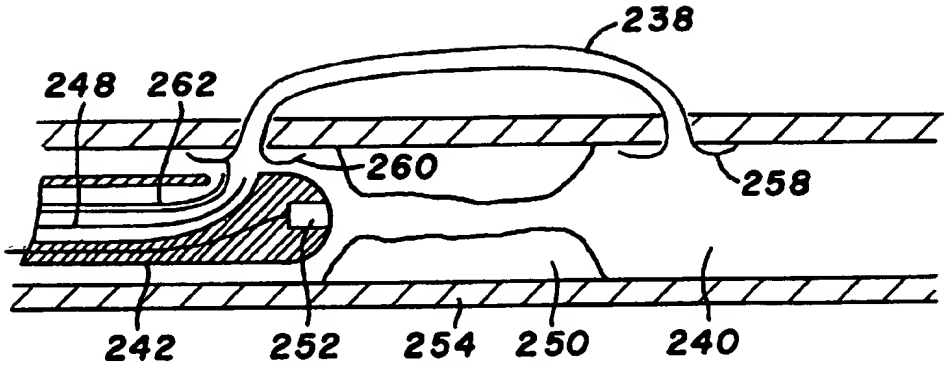


FIG. 29g

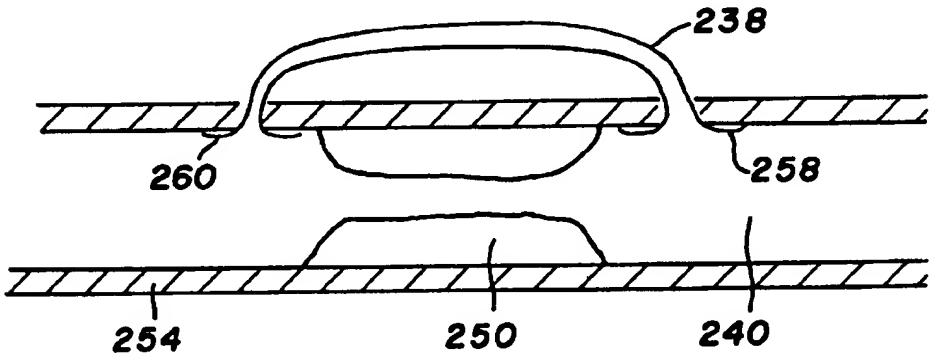


FIG. 29h

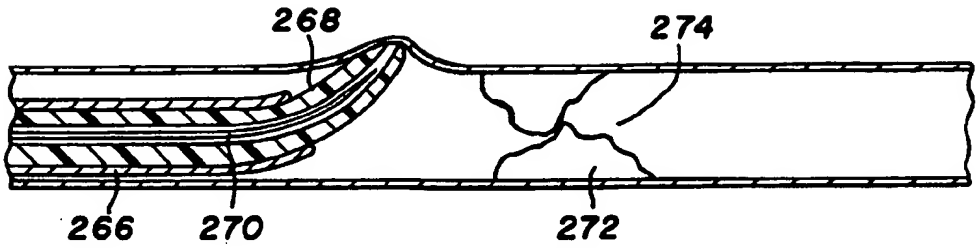


FIG. 30a

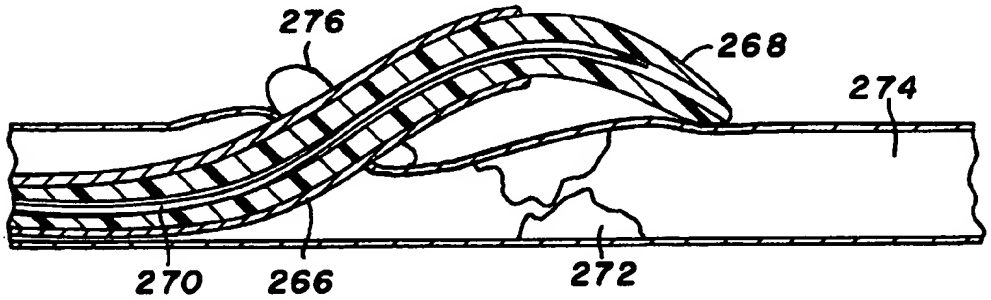


FIG. 30b

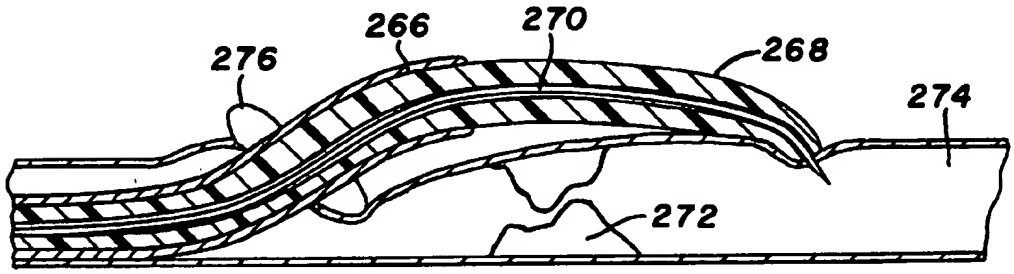


FIG. 30c

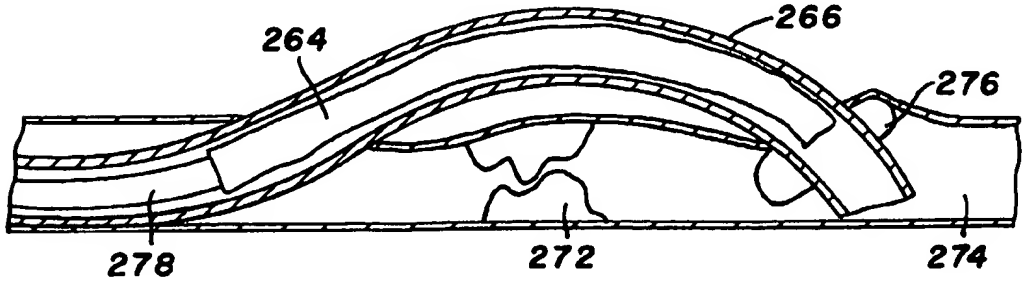


FIG. 30d

FIG.31a

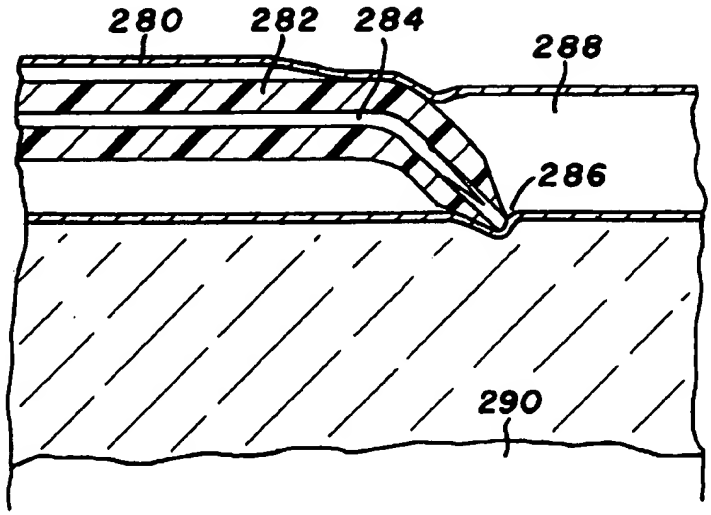


FIG.31b

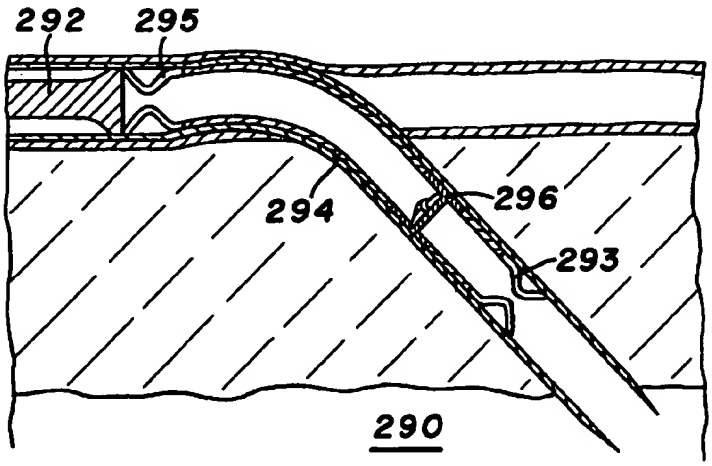
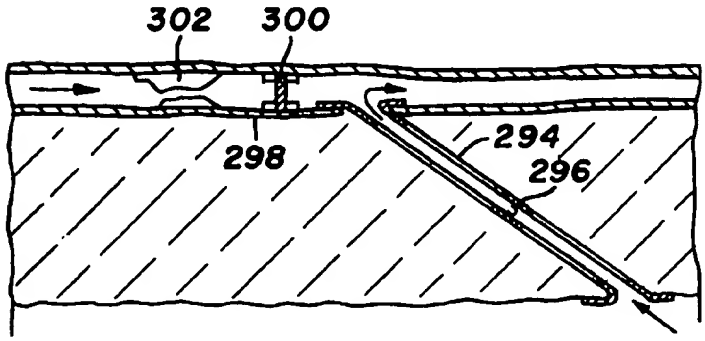


FIG.31c



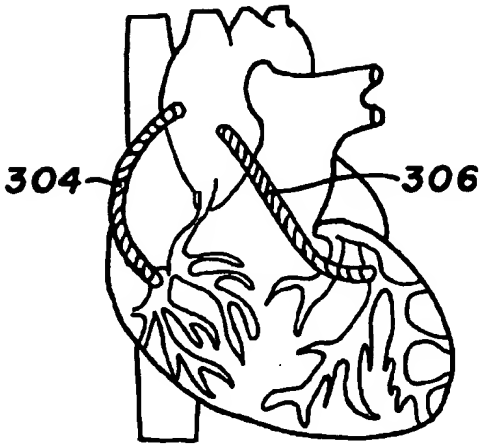


FIG. 32

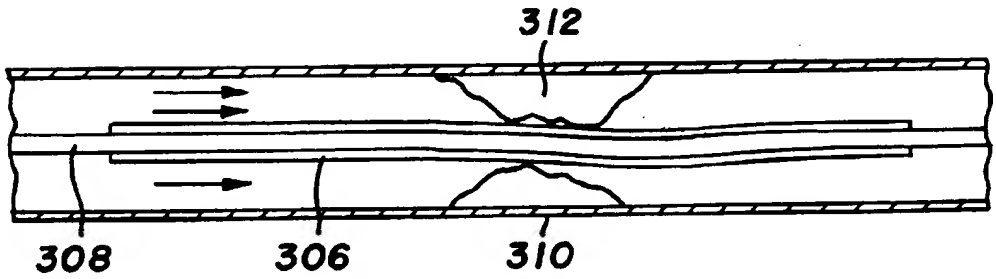


FIG. 33

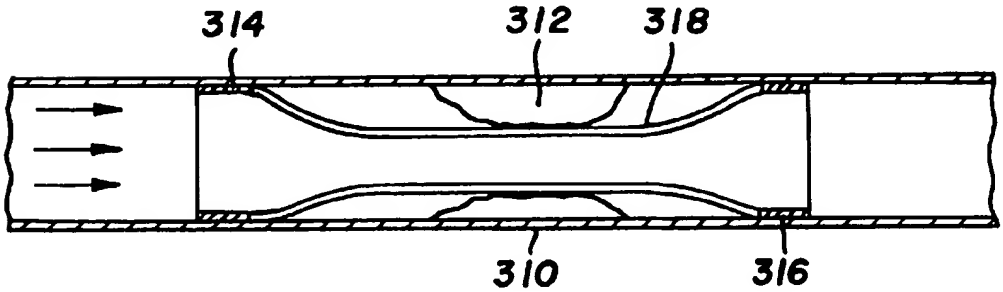


FIG. 34

PERCUTANEOUS BYPASS GRAFT AND SECURING SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 09/644,084 entitled Radially Expanding Prostheses and Systems for Their Deployment, filed Aug. 22, 2000, which is a continuation of U.S. patent application Ser. No. 08/932,566 entitled Radially Expandig Prostheses and Systems for Their Deployment, filed Sep. 19, 1997, now U.S. Pat. No. 6,149,681, which claims the benefit of Provisional Patent Application No. 60/026,592 entitled Self-Expanding Graft and Securing System, filed Sep. 20, 1996. This application also is a continuation of U.S. patent application Ser. No. 08/966,003, entitled Percutaneous Bypass Graft and Securing System, filed Nov. 7, 1997, now U.S. Pat. No. 5,989,276, and U.S. Provisional Application Serial No. 60/030,733 entitled Percutaneous Bypass Graft and Securing System, filed Nov. 8, 1996.

BACKGROUND OF THE INVENTION

The present invention relates to grafts implantable to bypass an obstruction or other undesirable condition within a vessel or other tubular organ, and more particularly to systems for deploying such grafts and fixation elements for securing them.

Bypass grafts are particularly useful in treating vascular diseases, but have other applications including treatment of urinary incontinence, infertility, and gastrointestinal defects such as occlusions and ulcers. Stenosed vessels cause ischemia which potentially leads to tissue infarction. Conventional techniques to treat partially occluded vessels include balloon angioplasty, stent deployment, and surgery to attach a graft to bypass the stenosed lesion. Surgical implantation of a bypass graft typically requires performing a thoracotomy, placing the patient on a cardiopulmonary bypass system, and using cardioplegia to induce cardiac arrest. This permits a suturing of the graft between cardiac vessels without the risk of excess blood loss or the need to accommodate motion of the heart. Less invasive attempts at positioning bypass grafts involve a thoracostomy to produce a conduit to the stenosed lesion. This approach uses endoscopic visualization to position the graft. The delivery for such graft requires modified surgical instruments (e.g., clamps, scissors, scalpels, etc.) and further involves ports inserted through small (approximately one inch) incisions to provide access into the thoracic cavity.

There remains a need for a minimally invasive technique for deploying and securing a bypass graft, and for a fixation means for more reliably securing a graft without the need to suture the graft.

Accordingly, it is an object of the present invention to provide a system for translumenal deployment of a bypass graft.

Another object is to provide a more effective fixation means for securing a deployed bypass graft.

A further object is to provide a system for bypass graft deployment, in which features incorporated within the graft reduce the time and difficulty of deployment.

Yet another object is to provide an improved process for deploying and securing grafts along body lumens to bypass obstructions and other undesirable features within the lumens.

SUMMARY OF THE INVENTION

To achieve these and other objects, there is provided a body implantable graft. The graft includes a tubular graft wall having opposite first and second open ends. The graft defines a fluid flow lumen between these ends. The tubular graft is adapted for a selected placement with the first end at a first location in body tissue and the second end at a second location in body tissue, to provide a fluid flow path between the first and second locations to bypass an obstruction between those locations. The graft also includes a graft fixation mechanism operable to heat the graft wall at least near the first end following placement, to thermally secure the graft wall and adjacent tissue.

The preferred fixation apparatus is an electrically conductive heating element mounted to the graft wall near the first end. The element can be annular, and may incorporate a feature to mechanically secure the graft, e.g., a collet or a grommet.

In similar fashion an electrically conductive heating element or other fixation apparatus can be used to secure the second end of the graft at the second location. The heating elements can be coupled to an RF power source and used in conjunction with an indifferent electrode, to secure the graft by ohmic heating.

Another aspect of the invention is a system for deploying a bypass graft. The system includes an elongate and flexible carrier having a proximal end and a distal end. The carrier is insertable by the distal end for intralumenal movement toward a selected site along a body lumen while the proximal end remains outside the body. A tissue perforating mechanism, near the distal end of the carrier, is positionable at a first location near the selected site, and operable from the proximal end of the carrier to form a first opening through tissue at the first location. Further, the mechanism is positionable at a second location near the selected site and operable to form a second opening through tissue at the second location. An elongate graft guide, supported by the carrier and disposed near the distal end, is movable into a guiding position in which the guide extends from the first location through the first opening to the second location and through the second opening. The system further includes a tubular graft adapted to be mounted to the carrier for movement along the carrier. A graft controller is operable to move the graft distally along the carrier toward the graft guide, and then distally along the graf guide when the guide is in the guiding position, to a bypass location in which the graft extends from the first location to the second location and also extends through the first and second openings.

The preferred carrier is a catheter having a catheter lumen. An elongate dilator is contained slideably within the lumen, and has a tapered distal tip. An elongate needle is slideably contained within the dilator.

According to one embodiment, the dilator provides the graft guide, while the tissue perforating mechanism includes the needle and the distal tip of the dilator.

According to another embodiment, a distal end region of the catheter provides the graft guide. The dilator and needle are used to perforate and dilate tissue to form the first and second openings. The dilator is not used to guide the graft, but is used to guide the catheter, particularly the distal, end region which in turn is used for positioning the graft after withdrawal of the dilator.

According to another aspect of the present invention, an alternative system is provided for implanting a bypass graft without the need for a catheter. This system includes a tissue dilating member having at its distal end a tissue dilating tip converging in the distal direction. A tissue puncturing tool is supported within the dilating member and extends in the distal direction from the dilating tip. The tool is adapted to

puncture or perforate a tissue wall to form an orifice enlargeable by the dilating tip. The system includes a graft with a substantially fluid impervious graft wall. First, second and third openings are formed through the graft wall at first, second and third spaced-apart regions of the wall, respectively. The graft is adapted for a removable mounting on the dilating member in which the dilating member extends through the first and third openings, with the first opening near the dilating tip and the third opening proximally of the first opening. This enables use of the dilating member to insert the first region of the graft wall into a first orifice in the tissue wall, for fixation of the first region in the first orifice. The graft further is slideable relative to the dilating member to permit a proximal withdrawal of the dilating member from the first region after its fixation, and further to allow an insertion of the dilating member into the second opening for securing the second region of the graft wall within a second orifice in the tissue wall. As a result, the graft provides a fluid flow conduit between the first orifice and the second orifice. A closure mechanism is provided for closing the third opening, following withdrawal of the dilating member from the graft, after the first and second regions have been secured.

Another aspect of the present invention is a process for translumenally deploying a bypass graft, including the following steps:

a. advancing an elongate catheter intralumenally toward a selected site along a body lumen;

b. with a distal end of the catheter near the selected site, using a tissue perforating mechanism mounted near a distal end of the catheter to form a first opening through a tissue wall defining the body lumen;

c. advancing tissue perforating mechanism through the first opening, and then to a selected location spaced apart from the first opening, then using the mechanism to form a second opening through tissue at the selected location;

d. advancing a graft guide through the first opening, distally to the selected location, then through the second opening;

e. with the graft guide so positioned, advancing a tubular graft along the guide to a bypass location in which the graft extends from the first opening to the second opening and through the first and second openings, thus to form a bypass conduit in fluid communication with the body lumen; and

f. while maintaining the graft in the bypass location, proximally withdrawing the catheter, the tissue perforation mechanism and the graft guide.

Thus, in accordance with the present invention, bypass grafts are deployed more easily using techniques that are considerably less invasive, and upon deployment are more reliably secured.

BRIEF DESCRIPTION OF THE DRAWINGS

For a further understanding of the above and other features and advantages, reference is made to the following detailed description and to the drawings, in which:

FIG. **1** is a side view, partially in section, of a bypass graft constructed according to the present invention an d secured within a vessel;

FIGS. **2–7** illustrate alternative couplings for mechanically fixing the opposite ends of bypass grafts;

FIG. **8** illustrates an alternative embodiment graft incorporating structural supports;

FIGS. **9–16** illustrate alternative embodiment grafts incorporating valves;

FIGS. **17** and **18** are side sectional views of a bypass graft and system for securing the graft to a vessel wall, in accordance with the present invention;

FIGS. **19** and **20** illustrate tissue dilators of alternative embodiment deployment systems employing thermal bonding;

FIG. **21** is a schematic illustration of a circuit for thermal bonding;

FIGS. **22–25** illustrate alternative embodiment dilators;

FIG. **26** illustrates a tissue perforating needle used with the dilators of the various deployment systems;

FIG. **27** is a sectional view of a needle and dilator contained within a catheter;

FIG. **28** illustrates an alternative embodiment dilator within a catheter;

FIGS. **29***a–h* illustrate a series of steps of a percutaneous deployment and fixation of a bypass graft according to the present invention;

FIGS. **30***a–d* illustrate an alternative deployment and fixation procedure;

FIGS. **31***a–c* illustrate a farther alternative deployment and fixation;

FIG. **32** shows several bypass grafts secured to the heart; and

FIGS. **33** and **34** illustrate an alternative graft secured within a vessel.

DESCRIPTION OF THE INVENTION

Turning now to the drawings, there is shown in FIG. **1** a bypass graft **16** secured within a blood vessel **18**, in a manner to bypass a lesion **20** within the vessel. Bypass graft **16** has a tubular wall **22** formed of a graft material, e.g., a polymer such as PTFE, urethane, polyimide, nylon, silicone, or polyethylene. The polymer may be extruded, blow molded, or dipped, and formed either directly into a tubing, or formed first as a sheet having opposed ends or edges bonded together to provide the tubular configuration. The edge bond can be formed by a variety of methods including ultrasonic welding, thermal bonding, sewing, adhesives, or with radio frequency (RF) energy. Alternatively, the graft can be a saphenous vein or other vessel from the patient.

At its proximal end **24**, bypass **16** incorporates a radially expandable stent **26**. The graft incorporates a similar stent **28** at its distal end region **30**. Once graft **16** is deploy the stents are radially expanded using a dilatation balloon or a mechanism such as those described in co-pending patent application Ser. No. 08/911,838 entitled "Mechanical Stent and Graft Delivery System," filed Aug. 15, 1997. Alternatively, the graft end regions can have a self-expanding structure, as described in U.S. Pat. No. 6,149,681 entitled "Radially Expanding Prostheses and Systems for Their Deployment," filed Sep. 20, 1996. More particularly, terminal ends may be provided that extent partially beyond the graft material. The terminal ends can be shaped in a variety of ways, such as in the form of flared end loops. In either event, each stent and its surrounding graft material are expanded into intimate contact with wall **22** of vessel **18**, thus to secure the graft.

As seen in FIG. **1**, graft **16** bypasses lesion **20**, in the sense that a medial region **32** of the graft is disposed outside of vessel **18**. For convenience, the graft can be considered to exit the vessel at an exit opening or orifice **34** through vessel wall **35**, and re-enter the vessel at a return opening or orifice **36**.

Tubular bypass grafts such as graft **16** can be secured within vessel walls or to other tissue by a variety of fixation mechanisms other than expandable stents. For example, FIG. **2** illustrates an annular collet **38** attached to one end of a graft **40**. The collet may be laminated or bonded to the graft, and is pre-formed to have a segment **42** extending radially beyond the graft. Segment **42** also is collapsible into a low profile to facilitate introduction through vasculature and deployment through the vessel wall. When released, the collet assumes the pre-formed configuration as shown. A portion **44** of the graft may extend along collet segment **42** to secure the vessel wall between the graft material and the collet and provide additional support for attaching the graft to the vessel.

FIGS. **3** and **4** illustrate a collet **46** in which the radially extending collet segment is comprised of eight radially extended collet members **48**. A membrane **50** may be joined to the collet members to prevent fluid flow through the tissue wall puncture site.

The collet may be made of stainless steel, a nickel-titanium alloy or thermoset plastic. It may be constructed with flattened tube nickel-titanium alloy or a braided pattern that is flared.

FIG. **5** shows a further alternative support mechanism in the form of an annular grommet **52** secured to end region **54** of a graft **56**. The grommet incorporates a convergence **58** to facilitate insertion through a vessel wall orifice, and a necked down feature **60** to capture the vessel wall immediately about the orifice.

As yet another mechanical fixation alternative, flexible bands **62** can be fixed to an end region of a graft **64** as shown in FIGS. **6** and **7**. Each band or other flexible member is compressible into the reduced profile shown in FIG. **6** and remains in that profile while constrained, e.g., by a surrounding catheter. When the graft is released from the catheter, band **62** assumes the radially enlarged, more circular profile shown in FIG. **7**. Pluralities of such bands can be provided in, crossing patterns at the graft ends, if desired.

For increased strength, particularly where a bypass graft is required to exert a radially outward force against a stenosed lesion, a blood vessel wall or other tissue, the graft can incorporate structural support members **66**. The support members can be constructed of metal or a polymer having a higher modulus of elasticity than the graft material. As shown in FIG. **8**, support members **66** can be distributed throughout the graft, with a greater density at the graft end regions to enhance fixation within openings through tissue. Support members **66** can have elliptical or rectangular profiles that enhance their strength in a selected direction.

If desired, such support members can be used in lieu of stents **26** and **28** for securing graft ends within a vessel. The support members may be laminated in the graft material. Fabrication can involve extruding or dipping an initial graft layer, winding the support members on the layer, then extruding or dipping to form a second layer covering the support members. Alternatively, the separate layers may be bonded together, or support members may be threaded through the graft material.

If desired, thermal bonding may be employed to augment the mechanical fixation and form a more positive fluid seal. More particularly, electrode strips **68** are mounted to the graft near the graft ends, and coupled through wires **70** to an energy source (e.g., an RF generator) which generates a current to heat adjacent tissue. When sufficient energy is supplied to the electrodes, the graft edges are thermally secured to the vessel all by a coagulation of the tissue to the electrode, or by desiccation of the vessel wall to provide an interference fit between the reduced-diameter vessel and the graft, especially where the graft and support members exert a radial force. This better secures the graft to the vessel wall and prevents leaks at the graft edges. Suitable materials for the electrodes, which are body compatible as well as electrically conductive, are platinum, platinum-iridium, stainless steel, and gold.

Once the graft has been sealed, signal wires **70** are removed from the graft by delivering a D.C. current through the signal wires at an amplitude sufficient to cause a breakdown of the signal wire, e.g., at a reduced-diameter weak point near its associated electrode. Alternatively, the signal wire can be cleaved, or mechanically removed by applying tension to sever the wire at a reduced-diameter neck region.

On occasion, it is desirable or necessary to ensure that flow of blood or other fluids through the graft is unidirectional. To this end, a valve may be placed within the graft, preferably along the medial region. FIGS. **9–16** show a variety of graft constructions.

Turning first to FIGS. **9** and **10**, a valve **72** includes a valve ball **74** within a surrounding structure that provides a valve seat **76** on one side of the ball, and upper and lower retainers **78** and **80** on the other side of the ball. In FIG. **9**, the valve is open and allows flow in the direction of the arrows, around the valve ball and through open spaces between the valve ball and surrounding structure in the area not occupied by the upper and lower retainers.

As shown in FIG. **10**, flow in the opposite direction is substantially prevented by a lodging of ball **74** against the valve seat. Further, the valve functions as a pressure relief valve in that the flow from left to right as viewed in the figure must be sufficient to overcome the tendency of retainers **78** and **80** to urge the ball valve against the valve seat.

FIG. **11** shows a valve **82** designed to react to the muscular contraction to restore normal vessel function. Muscular contraction forces the valve ends inward, opening the valve to permit fluid flow. The force required to open the valve may be selected, depending on the material, wall thickness, length, and geometry. A solid valve requires more force than a valve in which material is selectively removed to maintain the valve function yet decrease the required compressive force to open the valve.

FIGS. **12–14** show a one-way valve **84** having a membrane **86** that closes over valve support struts **88** when no external pressure is present. When pressure is applied due to a fluid flow, membrane **86** distends outwardly away from the struts as seen in FIG. **14**, permitting the flow of fluids. Fluid flow in the opposite direction (right to left as viewed in FIGS. **12** and **14**) is prevented.

The valves in FIGS. **9–10** and **12–14** act as pressure relief valves, in the sense that they may be tailored to require a selected force to open them, and they remain open only when the applied pressure exceeds the valve resistance. As a result, these valves characteristically remain open for short periods of time. Alternatively, FIGS. **15** and **16** show a pressure relief valve **90** that opens due to pressure exerted on the valve, and remains open until a compressive closure force is applied. Valve **90** includes a plunger **92** movable within a surrounding structure including a valve seat **94** and a knob structure **96** for retaining the valve against the valve seat. The outer structure, which can be the graft itself, includes a flexible section **98** including a protrusion **100** that can be flexed radially inwardly responsive to external pressure.

The knob structure maintains the valve closed until pressure against the valve, i.e., acting from left to right as viewed in FIG. **16**, exceeds a selected threshold and opens the valve to allow rightward flow. Even after such pressure subsides, the valve remains open until external, radially inward pressure is applied to compress flexible section **98** of the graft. This moves the plunger leftward, returning it beyond the knob structure against the valve seat, thus closing the valve once again.

Valve **90** is particularly well-suited for treating urinary incontinence. When bladder pressure exceeds the relief valve pressure threshold, the valve is opened to permit the flow of urine. When the bladder pressure is relieved, muscular contractions or other external squeezing flexes section **98** to return plunger **92** to the valve seat, thus closing the valve.

Systems for deploying grafts may require an incision, or alternatively may involve translumenal delivery for a substantially noninvasive procedure. In the latter case, the system must restrain the graft during introduction through sheathes positioned via the Seldinger technique or a surgical cut-down, advancement through the vasculature and into the target vessel. Unwanted perforations of the vessel or other tissue must be avoided. This requires flexibility to follow a guide wire positioned in the target vessel. Further, the system must facilitate easy and accurate deployment of the graft and delivery components. If a partially deployed graft needs to be altered as to location, the system should permit recapture and repositioning. Graft delivery systems may incorporate the capacity to mechanically create intimate contact of the graft with surrounded tissue, especially at the graft ends. This capability is discussed in the aforementioned application Ser. No. 08/911,838 entitled "Mechanical Stent and Graft Delivery System."

FIGS. **17** and **18** show a bypass graft deployment system **102** that requires an incision. The system includes a dilator **104** having a tapered (distally converging) distal tip **106**. A needle **108** is mounted coaxially within the dilator, and has a sharp cutting edge **110** for puncturing or perforating tissue. A bypass graft **112**, having a grommet **114** or other suitable fixation mechanism, is supported on and surrounds the dilator.

Use of system **102** requires an incision characteristic of a surgical cut-down, through the dermal layers near the vessel to provide an insertion port. Needle **108**, which can be slideably contained within the dilator if desired, is introduced into the. insertion port and punctures a wall **116** of a vessel **118** on one side of a stenosed lesion **120**. The dilator then is advanced over the needle to enlarge the puncture to provide an orifice for fixation of the graft. At this point, graft **112** is advanced over the dilator sufficiently to position grommet **114** within the orifice. Thus, a first region **122** of the graft is secured, so that an opening **124** of the graft is in fluid communication with vessel **118**.

As seen in FIG. **18**, graft **112** has two further openings: an opening **126** surrounded by graft material and a second grommet **128**; and a more proximally disposed opening **130**, where no grommet or other fixation device is provided.

Progress from the view of FIG. **17** to the view of FIG. **18** involves, in part, securing region **122** and grommet **114** as just described. Next, dilator **104** and needle **108** are withdrawn proximally, sufficiently to remove them from region **122**. Then, the dilator and needle are distally inserted through opening **126**, to become surrounded by grommet **128** and a graft region immediately about opening **126** as shown in FIG. **18**. At this point, needle **108** is advanced to puncture tissue wall **116**, and dilator **104** is used to enlarge the puncture, to form a second orifice on the opposite side of lesion **120**. Then, as shown in FIG. **18**, the dilator and graft are advanced sufficiently to position grommet **128** within the orifice.

After grommet **128** is secured, the dilator and needle are withdrawn from opening **126**, and further are withdrawn from a region **132** of the graft surrounding opening **130** so that the dilator and needle are completely free of the graft. Then opening **130**, which is provided only to allow access of the dilator and needle, is closed to prevent fluid leakage from the graft. One suitable closure mechanism is a purse-string, formed by threading a suture through the graft material in region **132**. Other closure mechanisms include staples or adhesives.

In multiple lumen applications, the bypass graft may have four or more openings to accommodate three or more fluid couplings to vasculature or organ cavities.

Alternative embodiment deployment systems use different approaches for graft fixation. For example, FIG. **19** shows a dilator **136** with a central lumen **138** for a needle (needle not shown). The dilator also incorporates a lumen **140**, through which a signal wire can extend for coupling with a dilator electrode **142**. Electrode **142** delivers RF energy to a grommet **144** at the distal end of a graft **146** surrounding the dilator, thus to thermally secure the grommet to a tissue wall **148** of a vessel **150**.

In FIG. **20**, a dilator **152** includes, along with a central needle lumen **154**, a signal wire lumen **156** and a balloon inflation lumen **158** open to a balloon **160** near the distal end of the dilator. The dilator supports a surrounding graft **162** having a collet **164** at its distal end.

Following insertion of the dilator through wall **166** of vessel **168**, balloon **160** is inflated to temporarily secure the dilator, which also bends a portion of collet **164** into the retaining position as shown. An electrode **170**, mounted on the exterior of balloon **160**, receives a current from a signal wire contained in lumen **156**, for thermally bonding collet **164** to the surrounding tissue. After thermal bonding, the balloon is deflated and the dilator withdrawn.

FIG. **21** illustrates a schematic circuit for ohmic heating of tissue, useable in conjunction with electrode **170**, other dilator supported electrodes, or electrodes mounted directly to a graft as previously described. An RF power generator **174** is coupled to the electrode through a signal wire **176**. An indifferent electrode **178**, spaced apart from electrode **170** and typically placed on a patient externally, is coupled to the RF generator through a conductor **180**. Thus, a current is generated through tissue between electrodes **170** and **178**, heating the tissue to form the bond.

FIGS. **22** and **23** are sectional views of a distal region of a dilator **182**, taken at different angles to show different lumens through the dilator. Lumens **184** and **186** in FIG. **22** accommodate signal wires to sensors or transducers **188** and **190** (further discussed below), which can be used to direct placement of the dilator at puncture sites. Sensor **188** is positioned for axial sensing, while a sensor **190** is oriented for lateral sensing. Several sensors **190** can be angularly spaced apart from one another about the dilator circumference.

Lumens **192** and **194**, shown in FIG. **23**, accommodate signal wires **196** to electrodes **198** used for thermal bonding.

As shown in FIG. **24**, a steering mechanism can be incorporated into the dilator to facilitate positioning of the dilator and needle for tissue perforations. In particular, a ring **198** is embedded in the dilator distal tip, surrounding needle

lumen **200**. A wire **202** is attached to ring **198**. By pulling wire **202**, the distal tip can be biased downwardly as viewed in the figure.

To further assist positioning, magnets may be incorporated into the dilator near its distal tip, as indicated at **206** for a dilator **208** shown in FIG. **25**. Such magnets may be formed of ferrite materials, or alternatively may be formed by winding conductive coils around the dilator to form electromagnets when current is supplied. The dilator magnets are used in conjunction with a guide wire **209** advanced beyond a stenosed lesion **210** within a vessel **212**. The guide wire is formed of metal, and to further enhance magnetic attraction may incorporate a magnet **214** of opposite polarity to the dilator magnet. Magnetic positioning facilitates placing bypass grafts through tortuous vessels or over long distances beyond the lesion. Alternatively, known imaging techniques can be used to locate the dilator magnets.

As seen in FIG. **26**, a needle also can be provided with steering capability, in particular by forming a hollow needle **216** and securing a wire **218** to a distal portion of a needle through a weld or solder joint **220**. A sensor **222** at the needle tip, coupled to wires **224** contained within the needle lumen, can be used to sense a position of the needle tip. A further needle enhancement is a stop **226**. When open as shown in FIG. **26**, stop **226** limits the degree to which needle **216** can be inserted into tissue, thus preventing excessive, damaging perforations. At the same time, stop **226** is collapsible into a diameter substantially the same as that of the needle when the needle is withdrawn into a dilator.

Intralumenal graft deployment systems also utilize dilators and needles as described, but further incorporate catheters. A suitable arrangement, as shown in FIG. **27**, includes a needle **228** surrounded by a dilator **230**, which in turn is surrounded by a catheter **232**, all components being coaxial and circular in profile.

An alternative arrangement, shown in FIG. **28**, incorporates non-circular features into a dilator **234** and a lumen of a catheter **236**. The non-circular matching features allow transmittal of torque from catheter **236** to dilator **234**, enabling selective rotation of the dilator by rotating the catheter.

FIGS. **29***a*–**29***h* illustrate progressive steps in a percutaneous, intralumenal deployment of a graft **238**, to bypass a lesion in a vessel **240**. The system includes a catheter **242** with a lumen **244** containing graft **238**, a dilator **246** and a needle **248** within the dilator.

First, the catheter and other components are advanced intralumenally to the proximal side of lesion **250** as shown in FIG. **29***a*. Sensors **252** facilitate positioning. Such sensors can include ultrasonic transducers of piezoelectric material, infrared transducers, or fiber-optic elements. Alternatively, a radiopaque contrast material may be injected to enhance fluoroscopic visualization.

As seen in FIG. **29***b*, needle **248** is advanced to puncture vessel wall **254**. A stop **256** restricts movement of a needle if necessary. Then, dilator **246** is advanced, collapsing stop **256** and enlarging the puncture to provide a suitable orifice through the vessel wall. The orifice and dilator tend to form a seal, preventing excess blood leakage as the dilator is advanced along and outside of the vessel. The dilator may have a pre-shaped distal end to facilitate positioning, as shown in FIG. **29***c*.

When the dilator has been advanced to a point near a selected re-entry location, needle **248** is advanced beyond the dilator to puncture vessel wall **254** (FIG. **29***d*). Once again, stop **256** prevents excessive needle advancement, if necessary. Alternatively the stop can limit needle travel relative to the dilator. At this point, dilator **246** is advanced over the needle (FIG. **29***e*), collapsing the stop and enlarging the puncture by its distal tip, entering the vessel once again. At this time, needle **248** may be completely retracted if desired.

As seen in FIG. **29***f*, graft **238** then is advanced over dilator **246**, until the graft reenters the vessel, i.e., has its opposite ends contained, each in its respective orifice. A collet **258** at the distal end of the graft prevents graft retraction, and a collet **260** anchors the proximal end of the graft. At this point, the dilator can be retracted back into catheter **242**, as shown in FIG. **29***g*. A hollow stylet **262** is used to advance the graft, and also to maintain the graft in place during subsequent withdrawal of the dilator. Finally, the catheter, stylet and dilator are withdrawn, leaving graft **238** secured, as seen in FIG. **29***h*.

FIGS. **30***a*–*d* show an alternative system and graft deployment process, in which a graft **264** is guided to its bypass location within a catheter rather than over a dilator. The system includes a catheter **266** containing a dilator **268**, which in turn contains a puncturing needle **270**. These components are advanced to a position proximate a lesion **272** within a vessel **274**. Dilator **268** is pre-formed with a bend at its distal region, and when positioned as shown in FIG. **30***a*, is directed upwardly toward the vessel wall as shown, to direct the needle toward the first intended puncture.

After puncture and dilation with the dilator tip, dilator **268** can be advanced over the needle, outside of and along the vessel. The dilator is rotated, preferably by the catheter using non-circular profile features as described above, to reorient the tip and point it back toward the vessel as shown in FIG. **30***b*. Catheter **266** is advanced along the dilator, through the orifice and outside of the vessel. A balloon **276** surrounding the catheter can be inflated at this point, to maintain the catheter against proximal withdrawal.

Then, with the tip of dilator **268** positioned against the vessel wall at the desired puncture location, needle **270** is advanced to form the puncture for a re-entry orifice (FIG. **30***c*). The dilator tip is used to enlarge the orifice, permitting advancement of the dilator into vessel **274**, followed by advancement of catheter **266** over the dilator, through the orifice and into the vessel as well. Balloon **276** can be reinflated at this point, to temporarily secure the catheter.

With the catheter secured, the dilator and needle are withdrawn, leaving the catheter alone as in FIG. **30***d*. At this stage, and after withdrawal of the dilator and needle, a graft can be inserted into the catheter and moved distally along the catheter using a stylet **278**, until the graft reaches a bypass location in which each end of the graft is contained within its respective orifice. Withdrawal of the catheter (not shown), while the stylet maintains the graft in the bypass location, allows collets or other fixation mechanisms to expand and secure the graft.

This procedure is particularly suited for smaller lesions, where the dilator need travel only a short distance along the vessel.

FIGS. **31***a*–*c* illustrate a further alternative system and procedure for forming a bypass from a vessel to an organ cavity. Initially, a catheter **280** containing a dilator **282** and a needle **284** is advanced to an intended puncture site **286** within a vessel **288**. The puncture is formed as previously described, and the dilator is advanced through tissue to an organ cavity **290**. Then, the catheter is advanced over the dilator, becoming open to the cavity as shown in FIG. **31***b*.

This permits use of a stylet **292** to advance a graft **294** through the catheter, until the catheter extends completely through the tissue to the cavity. Collets **293** and **295** secure the catheter. A valve **296** within the catheter limits flow to the direction indicated by the arrow. A graft **298** incorporating a valve **300** is positioned near lesion **302**, to prevent backflow toward the lesion.

FIG. **32** illustrates two bypass grafts **304** and **306** used to couple the aorta to coronary vasculature in accordance with the present invention.

FIG. **33** illustrates a graft **306** collapsed around a catheter body **308**, deployed in a target vessel across a stenosed lesion **310**. The catheter and graft are translumenally advanced to the position shown. The opposite ends of the graft contain expandable stents **314** and **316**, expanded in place with a mechanism such as those described in the aforementioned application Ser. No. 08/911,838. Alternatively, the graft ends can have self-expanding characteristics.

FIG. **34** shows the graft expanded. The ends are fully expanded into intimate contact with the vessel wall. However, along a medial region **318**, graft **306** is expanded only to a nominal diameter. The diameter is selected to reduce the flow of resistance and increase cardiac output, yet prevent damage to the endothelial wall. For example, a 50% expansion usually is sufficient to open the vessel while preventing excess damage. A large space between the exterior of the graft and the vessel wall accommodates growth of the stenosed lesion, and tends to contain such growth along the vessel wall so that the vessel remains open. To accomplish this, graft **308** should have inherent radial stability, for example, by employing structural supports as previously discussed.

If desired, graft structural stability and fixation can be enhanced by forming grafts with two or more layers, with pockets formed between the layers to contain biocompatible foams which solidify when activated to provide further support. Drug solutions also can be provided in such pockets.

To improve graft radial expansion in conjunction with using the graft of FIGS. **33** and **34**, channels may be formed through the lesion by cutting a slit through the vessel wall in the targeted region. A mechanical deployment system as described in the aforementioned patent application Ser. No. 08/911,838 can be used to form the required channel.

Thus, in accordance with the present invention, a more easily deployed graft is more reliably secured, to effectively bypass lesions and other blockages.

The patent applications cited herein are incorporated by reference, each in its entirety and for all purposes.

We claim as our invention:

1. An anastomotic connector system for connecting a tubular graft to a blood vessel or hollow body organ comprising:

a collet comprising a tubular collet portion having a proximal end and a distal end, and a plurality of radially self-expanding collet members separate from each other and disposed around the distal end of the tubular collet portion and depending therefrom,

each of the collet members having a proximal end and a distal end, the distal end of each collet member having a blunt configuration so as to extend along a vessel or body organ wall interior.

2. The connector system of claim **1** additionally comprising a tubular graft joined to the collet.

3. The connector system of claim **2** wherein the graft is laminated to the collet.

4. The connector system of claim **2** wherein the graft is bonded to the collet.

5. The connector system of claim **2** wherein the graft is joined to the collet over an outer surface of the collet tubular portion proximal end, overlapping a vessel or organ wall.

6. The connector system of claim **1** wherein the collet comprises a memory elastic material.

7. The connector system of claim **1** wherein the collet comprises a material selected from the group consisting of stainless steel, nickel titanium and thermoset plastic.

8. The connector system of claims **1** wherein the self-expanding collet members comprise a memory elastic material.

9. The connector system of claim **1** wherein the self-expanding collet members comprise a material selected from the group consisting of stainless steel, nickel titanium and thermoset plastic.

10. The connector system of claim **1** wherein the collet is capable of expanding into an expanded profile from a collapsed first profile.

11. The connector system of claim **1** wherein the self-expanding collet members are configured to self-expand from a first confined position substantially colinear to the tubular collet portion to a second unconfined position extending radially outward upon release from the first confined position.

12. The connector system of claim **11** wherein the self-expanding collet members form an angle with the tubular collet portion of between about 45 degrees and 120 degrees when in the second unconfined position.

13. The connector system of claim **12** wherein the angle is about 90 degrees.

14. The connector system of claim **1** wherein the self-expanding collet members are adapted to attach a graft to a vessel or organ wall interor by direct contact between the self-expanding collet member and the vessel or organ wall interior without penetrating the vessel or organ wall interior.

15. The connector of claim **14** wherein the at least one collet member is configured to bow outward to exert force against a vessel or organ wall and support a graft within a lumen defined by the vessel or organ wall.

16. The connector system of claim **1** additionally comprising a membrane disposed about at least a portion of the collet members.

17. The connector system of claim **16** wherein the membrane is at least partially impervious to fluid flow therethrough.

18. The connector system of claim **1** additionally comprising a membrane forming a substantially fluid-impervious layer disposed about at least a portion of the collet members such that when said connector is deployed at a vessel or organ puncture site, said membrane substantially prevents fluid flow through the puncture site.

19. The connector system of claim **18** wherein the covering forms a continuous, annular, fluid-impervious layer.

20. The connector of claim **1** wherein said collet members comprise segments extending from said tubular collet portion.

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